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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,095	FORTUNE ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53 and 63-67* is/are pending in the application.

4a) Of the above claim(s) *11,31-53 and 63-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/4/2005 and 2/12/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-30) in the reply filed on 3/20/2008 is acknowledged. Applicant's election of the following is also acknowledged (i) as the tissue-reactive functional group, N-hydroxysuccinimide esters; and (ii) a material formed by derivatization of a polymer precursor, where the derivatized polymer is a co-polymer of N-vinyl-2-pyrrolidinone and acrylic acid.

The traversal is on the ground that Groups I and II are related as subcombination/combination, and the combination of Claim 31 requires each and every limitation of Claim 1. This is not found persuasive because the standard for restriction practice in applications filed under 35 U.S.C. 371 is lack of unity. The office action mailed 2/26/2008 set forth the reasons for lack of unity (see pages 2-3).

The requirement is still deemed proper and is therefore made FINAL. Claims 1-10, 12-22 and 28-30 are currently under consideration.

In the search for the elected species, prior art applicable to non-elected species was discovered. This discovery is not an indication that the full scope of the claims have been examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 and 12-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims recite the phrase "wherein the material... formed by derivatization of a polymer precursor". The specification lacks chemical structural information for what materials are encompassed by this phrase and such structures would be highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus of a "material... formed by derivatization of a polymer precursor", since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a derivative.

The appearance of mere indistinct words (here the word "inhibitor") in a specification or a claim, even an original claim, does not necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004). A description of what a material does, rather than of what it is, usually does not suffice to provide an adequate written description of the invention. Univ. of Cal. v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines

stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003). No such correlation has been disclosed here; at best all that can be inferred from the instant specification is that compounds having the general formulae set forth at page 5 of the specification inhibit the production of downstream products of 14 kD PLA2, such as arachidonic acid. See the first paragraph on page 13. Whether this was specifically due to inhibition of enzyme activity, or also due inhibition of production, transcription or translation, or some combination of these, is not clear from the data presented.

The examiner recognizes that the fact situation in the Rochester cases was extreme, with Applicant disclosing there no (or possibly one) specific compounds. The reasoning provided by the court can be fairly extended to less extreme situations (*i.e.*, where a limited number of species is actually disclosed, such as here), however, given the court's recognition that:

> [I]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. Rochester (2003) at 1431.

As was the case in Rochester, there is no such specificity here, nor could one skilled in the art identify any particular compound, other than those having the general formula set forth at the top of page 5 of the specification, as being able to inhibit any particular mechanism of 14 kDa PLA_2 action, other than to inhibit its "activity" in some unspecified way.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 6, 7, 21 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "the ratio… is between..." in Claims 2 and 3 is vague and indefinite. It is unclear if this is a molar ratio, a volume ratio, etc.

The phrase "type(s) of material" in Claims 6 and 7 is vague and indefinite. The specification does not allow one skilled in the art to determine what differentiates a given "type" of material from another.

The phrase "a molar ratio of acrylic-acid derived units between 0.05 and 0.50 and vinyl pyrrolidone-derived units between 0.50 and 0.95" in Claim 21 is vague and indefinite. It is unclear what each ratio is relative too.

Claim 29 recites the phrase "components selected from the group of structural polymers, surfactants, plasticisers, and excipients". A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by

such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claim 29 recites the broad recitation "excipients", and the claim also recites "structural polymers, surfactants, plasticisers" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12-16, 19-20, and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 3502998 (hereafter DE '998; a machine translation is provided). DE '998 discloses a formulation (tissue-adhesive formulation) comprising ferromagnetic particles of ferrite (synthetic cross-linkable material in particulate form) in admixture with poly(N-vinyl-2-pyrrolidone-co-acrylic acid) co-polymer bearing N-hydroxysuccinimide esters (particulate material comprising tissue-reactive functional groups) (see machine translation: page 2, third and fifth paragraphs; Example 1). The particle diameters range from 0.5 to 1 micron (see ibid; page 2, first paragraph). The poly(N-vinyl-2-pyrrolidone-co-acrylic acid) co-polymer bearing N-hydroxysuccinimide esters is

prepared by treatment with 2,2'-azobisisobutyronitrile (a free radical initiator (see machine translation: Example 1). The formulation is mixed with proteins, which the examiner is interpreting as a form of structural polymer (see ibid; Instant Claim 29).

DE '998 does not disclose the pH of the cross-linkable material (see Instant Claim 28). The buffering of the cross-linkable material at any time is not a limitation which materially effects the formulation disclosed by the instant claims. Examiner finds it reasonable, however, that the cross-linkable material disclosed by DE '998 was around a pH of 7 at the time the poly(N-vinyl-2-pyrrolidone-co-acrylic acid) co-polymer bearing N-hydroxysuccinimide esters was added.

DE '998 does not disclose the use of the formulation as a tissue-adhesive formulation, but rather for injection into a patient to treat cancer. A recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the formulation disclosed by DE '998 is full capable of performing the intended use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-10, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6989192 (hereafter '192). '192 discloses a pressure sensitive adhesive formulation (a tissue-adhesive formulation) comprising cross-linkable polyacrylate particles (a synthetic cross-linkable material) in admixture with particles comprising a material comprising a functional group X, wherein X is preferably an aldehyde (a particulate material comprising tissue-reactive functional groups) (see

abstract; col 2, line 50 to col 3, line 34; Claims 1-16). The material comprising a functional group X is comprised of monomers selected from vinyl, acrylic and/or methacrylate monomers, and is a reasonable embodiment of the phrase "a material… formed by derivitization of a polymer precursor" in Instant Claims 8-10 (see ibid; Claim 13). The particles have a particle diameter of 50 to 200 microns (see col 4, lines 5-8; Claim 6). '192 fails to disclose an example or specific combination of the formulation wherein X is an aldehyde.

It would be obvious to one of ordinary skill in the art at the time the invention was made to prepare a formulation comprising cross-linkable polyacrylate particles in admixture with particles comprising a material comprising an aldehyde, with a reasonable expectation of success, as this is an embodiment of the formulation disclosed by '192, to afford an improved pressure sensitive adhesive formulation.

Claims 17-18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 3502998 (hereafter DE '998; a machine translation is provided) in view of WO 2003094898 (hereafter WO '898). As stated above, DE '998 discloses a formulation (tissue-adhesive formulation) comprising ferromagnetic particles of ferrite (synthetic cross-linkable material in particulate form) in admixture with poly(N-vinyl-2-pyrrolidone-co-acrylic acid) co-polymer bearing N-hydroxysuccinimide esters (particulate material comprising tissue-reactive functional groups). DE '998 fails to disclose a molar ratio of acrylic acid-derived units nor vinyl pyrrolidone-derived units.

WO '898 discloses biomedical applications of poly(N-vinyl-2-pyrrolidone-co-acrylic acid) co-polymers (see page 6, lines 5 to page 8, line 23; Examples). WO '898 further discloses that an optimum molar ratio of ionically crosslinkable polymeric material (N-vinyl-2-pyrrolidone) to ethylenically unsaturated molecule (acrylic acid) to be from about 1:1 to about 20:1 (see Claim 7). The Examiner is interpreting these ranges to be encompassed by the ranges disclosed in the instant claim.

It would be obvious to one of ordinary skill in the art at the time the invention was made to optimize the ratio of acrylic acid and vinyl pyrrolidone in the formulation disclosed by DE '998 through routine experimentation to 1:1 to about 20:1, with a reasonable expectation of success to afford an improved biocompatible poly(N-vinyl-2-pyrrolidone-co-acrylic acid) co-polymers.

Claims 22 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 3502998 (hereafter DE '998; a machine translation is provided). As stated above, DE '998 discloses a formulation (tissue-adhesive formulation) comprising ferromagnetic particles of ferrite (synthetic cross-linkable material in particulate form) in admixture with poly(N-vinyl-2-pyrrolidone-co-acrylic acid) co-polymer bearing N-hydroxysuccinimide esters (particulate material comprising tissue-reactive functional groups). The particle diameters range from 0.5 to 1 micron. DE '998 fails to disclose the concentration of the poly(N-vinyl-2-pyrrolidone-co-acrylic acid) co-polymer bearing N-hydroxysuccinimide esters. DE '998 further fails to disclose particle diameters range from 5 to 500 microns.

It would be obvious to one of ordinary skill in the art at the time the invention was made to optimize the above parameters to afford an improved formulation. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

March 29, 2008